UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,658	07/22/2002	Alvin Berger	3712161.00044	6858

29157 7590 08/24/2010

K&L Gates LLP
P.O. Box 1135
CHICAGO, IL 60690

EXAMINER	
EBRAHIM, NABILA G	

ART UNIT	PAPER NUMBER
1618	

NOTIFICATION DATE	DELIVERY MODE
08/24/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

chicago.patents@klgates.com

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
U.S. Patent and Trademark Office
Address : COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO./ CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR / PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.
10/089,658	07/22/2002	ALVIN BERGER et al.	

K&L Gates LLP
P.O. Box 1135
CHICAGO, IL 60690

EXAMINER	
EBRAHIM, NABILA	
ART UNIT	PAPER NUMBER
1618	
MAIL DATE	DELIVERY MODE
08/20/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte ALVIN BERGER and GAYLE CROZIER

Appeal 2010-000375
Application 10/089,658
Technology Center 1600

Before DONALD E. ADAMS, DEMETRA J. MILLS, and MELANIE L. McCOLLUM, *Administrative Patent Judges*.

McCOLLUM, *Administrative Patent Judge*.

DECISION ON APPEAL[1]

This is an appeal under 35 U.S.C. § 134 involving claims to a composition for oral administration and its method of production. The Examiner has rejected the claims as obvious. We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

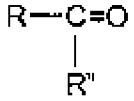
---

[1] The two-month time period for filing an appeal or commencing a civil action, as recited in 37 C.F.R. § 1.304, or for filing a request for rehearing, as recited in 37 C.F.R. § 41.52, begins to run from the "MAIL DATE" (paper delivery mode) or the "NOTIFICATION DATE" (electronic delivery mode) shown on the PTOL-90A cover letter attached to this decision.

STATEMENT OF THE CASE

Claims 1, 3-11, 13-16, and 18-22 are pending and on appeal (App. Br. 4). The claims subject to each rejection have not been argued separately and therefore stand or fall together. 37 C.F.R. § 41.37(c)(1)(vii). We will focus on claims 1 and 14, which read as follows:

1. A composition for oral administration, comprising a steroidal or non-steroidal anti-inflammatory drug (NSAID) and a naturally occurring precursor that is metabolised to a compound having anandamide activity for use as a medicament, wherein the precursor comprises a long chain polyunsaturated fatty acid (LCPUFA) which is a polyunsaturated fatty acid of 16-28 carbon atoms having from 2 to 6 double bonds, and having a moiety selected from the group consisting of methyl-, branched-, cyclic-, conjugated-, non-methylene interrupted-, epoxy-, furanoid-, hydroxyl-, allylic-, trans-, and seleno, or wherein the precursor is a LCPUFA or derivative thereof of the general formula X:



wherein R is the alkenyl moiety of the LCPUFA of total chain length 16-28 carbon atoms with 2-6 double bonds, with the first double bond at the c-1, c-3, c6, c7, c9, c12 position, counting from the non carboxyl (methyl) part of the molecule; and where R" is selected from the group consisting of -H, lower alkyl, -OH, NH_3, and an acid addition salt or complex thereof.

14. A method for producing a nutritional or therapeutic composition for oral administration comprising the steps of obtaining a therapeutically effective amount of a naturally occurring precursor that is metabolised to a compound having anandamide activity, obtaining a steroidal or non-steroidal anti-inflammatory drug (NSAID), and preparing a composition including the precursor and the steroidal or non-steroidal anti-inflammatory drug (NSAID).

Claims 1, 3-11, and 13 stand rejected under 35 U.S.C. § 103(a) as obvious over Di Marzo[2] in view of Burch[3] (Ans. 3).

Claims 14-16 and 18-22 stand rejected under 35 U.S.C. § 103(a) as obvious over Di Marzo in view of Burch and Kyle[4] (Ans. 5, as corrected in the communication mailed July 14, 2009).

I

In rejecting claim 1, the Examiner relies on Di Marzo for teaching that an "alternative precursor for arachidonic acid, 2-arachidonoyl-glycerol has cannabimimetic activity" and that a composition comprising this precursor has "led to the proposition of a role of the monoglyceride as an 'endocannabinoid'" (Ans. 4). The Examiner finds that Di Marzo "[a]lso considered . . . possible interactions with another arachidonic acid-derived endogenous cannabinoid, anandamide" (*id.*).

The Examiner relies on Burch for teaching "that combinations of analgesic drugs cause synergism of its analgesic effect" (*id.* at 5). The Examiner finds that "Burch exemplifies the combinations by using oxycodone and NSAID's (rofecoxib)," but concludes that it would have been obvious "to combine an anandamide and/or an anandamide precursor with NSAID's to enhance the analgesic effect of both drugs" (*id.*). The Examiner also finds that it would have been "a good motivation to the skilled artisan to replace oxycodone with anandamide as anandamide

---

[2] V. Di Marzo, *REVIEW: 2-Arachidonoyl-glycerol as an "Endocannabinoid": Limelight for a Formerly Neglected Metabolite*, 63 BIOCHEMISTRY (MOSCOW) 13-21 (1998) (as translated).
[3] Burch et al., US 6,552,031 B1, Apr. 22, 2003.
[4] Kyle, WO 94/28913 A1, Dec. 22, 1994.

derivatives and precursors do not have the addictive characteristics of oxycodone" (*id.*).

Appellants argue that "the Examiner fails to establish a *prima facie* case of obviousness because there exists no reason that the skilled artisan would have combined the cited references to arrive at the presently claimed subject matter" (App. Br. 13). In particular, Appellants argue that "the skilled artisan would have no reason to replace oxycodone[, an opioid analgetic,] with anandamide to arrive at the present claims" (*id.*). Appellants also argue that "the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified" (*id.* at 15). In addition, Appellants argue that "*Burch* specifically teaches away from the claimed subject matter when *Burch* teaches that a COX-2 inhibitor (such as rofecoxib) 'would have advantages over NSAID'S'" (*id.* at 15-16 (quoting Burch, col. 3, ll. 58-60)). Appellants also argue that "the Examiner has improperly applied hindsight reasoning by attempting to selectively piece together teachings of each of the references in an attempt to recreate what the claimed invention discloses" (*id.* at 16).

Issue

Does the evidence support the Examiner's conclusion that it would have been obvious to combine Di Marzo's precursor with an NSAID?

Findings of Fact

1. Di Marzo discloses that 2-arachidonoyl-glycerol (2-AG) has attracted renewed interest because of findings of its cannabimimetic activity and recent landmarks have led to the proposition of a role of this monoglyceride as an "endocannabinoid" (Di Marzo, Abstract).

2. Di Marzo also discloses that analgesia, hypothermia, and inhibition of motor behavior were observed when 2-AG was co-administered with a mixture of 2-palmitoyl- and 2-linoleoyl-glycerol, which alone have no effect in these behavioral tests (Di Marzo 9-10[5]).

3. Burch discloses

> Prior publications report that analgesic potency may be improved while reducing undesirable effects by combining an opioid with an NSAID or an analgesic such as acetylsalicylic acid or acetaminophen, in such a way as to obtain a synergistic analgesic effect allowing for a reduction in the total dose of both the NSAID and analgesic.

(Burch, col. 2, ll. 7-12.)

4. Burch discloses, however, that a "COX-2 inhibitor would have advantages over NSAID'S such as a diminished ability to induce some of the mechanism-based side effects" (*id.* at col. 3, ll. 58-60).

5. Thus, Burch discloses "analgesic pharmaceutical compositions comprising a COX-2 inhibitor together with an opioid analgesic" (*id.* at col. 4, ll. 58-60).

6. Burch discloses that the "invention allows for the use of lower doses of the opioid analgesic or the COX-2 inhibitor . . . or lower does of both drugs . . . than would normally be required when either drug is used alone" (*id.* at col. 4, l. 66, to col. 5, l. 3).

7. Specifically, Burch discloses a pharmaceutical composition comprising a dose of rofecoxib, a COX-2 inhibitor, and a dose of

---

[5] The page citation refers to the pages of the translation of record.

oxycodone, an opioid analgesic (*id.* at col. 30, ll. 20-24, col. 9, ll. 37-40, & col. 13, ll. 20-22).

Principles of Law

"The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." *KSR Int'l v. Teleflex Inc.*, 550 U.S. 398, 416 (2007). However, a proposed modification or combination of the prior art that would change the basic principles under which the prior art invention was designed to operate weighs against a conclusion of prima facie obviousness. *In re Ratti*, 270 F.2d 810, 813 (CCPA 1959).

> A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant. The degree of teaching away will of course depend on the particular facts; in general, a reference will teach away if it suggests that the line of development flowing from the reference's disclosure is unlikely to be productive of the result sought by the applicant.

In re Gurley, 27 F.3d 551, 553 (Fed. Cir. 1994).

Analysis

Di Marzo discloses that 2-AG is an endocannabinoid providing analgesia (Findings of Fact (FF) 1-2). Burch discloses that it was known in the art to combine an analgesic with an NSAID to allow the use of lower doses of one or both drugs (FF 3 & 5-7). We agree with the Examiner that it would have been prima facie obvious to combine 2-AG with an NSAID to enhance their analgesic effect (Ans. 5).

We do not dispute Appellants' contention that "opio[i]d analgetics and antimimetics . . . comprise pharmaceutically different effective groups characterized by different mechanisms of action" (App. Br. 14). However, we disagree with Appellants' position that it would not have been prima facie obvious to substitute one analgesic for another, even if they work in different ways. "The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." *KSR Int'l v. Teleflex Inc.*, *supra*.

In addition, we do not agree that the modification or combination would change the principle of operation of the prior art invention being modified. Granted, the mechanism by which 2-AG provides analgesia may be different from the mechanism of an opioid analgesic. However, both operate is the same basic way, that is, by being administered to a patient.

We also do not agree that Burch teaches away from the claimed invention. Burch discloses that a "COX-2 inhibitor would have advantages over NSAID'S" (FF 4). However, Burch does not disclose that traditional NSAIDs are unlikely to be productive. Moreover, claim 1 encompasses "a steroidal or non-steroidal anti-inflammatory drug." Appellants have not explained why this recitation would not include a COX-2 inhibitor, such as rofecoxib.

Conclusion

The evidence supports the Examiner's conclusion that it would have been obvious to combine Di Marzo's precursor with an NSAID. We therefore affirm the obviousness rejection of claims 1, 3-11, and 13.

II

In rejecting claim 14, the Examiner relies on Di Marzo and Burch as discussed above (Ans. 5). The Examiner relies on Kyle for disclosing a preparation method (*id.* at 6). The Examiner concludes that it would have been obvious "to purify the naturally occurring arachidonic acid derivative disclosed by [Di] Marzo . . . to treat different disorders . . . and make an oral therapeutic product as disclosed by Kyle to advance the treatment of these ailments and facilitate . . . patients taking their therapeutic needs in an easy oral dosage form or nutrient" (*id.* at 6-7).

Appellants argue that Kyle fails to remedy the deficiencies of Di Marzo and Burch (App. Br. 16). Because we are not persuaded that Di Marzo and Burch are deficient, we are not persuaded by Appellants' argument. We therefore affirm the obviousness rejection of claims 14-16 and 18-22.

TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED

cdc

K&L Gates LLP
P.O. Box 1135
CHICAGO, IL 60690